Summary of the Proficiency Testing Committee Teleconference November 7, 1996

The Proficiency Testing (PT) Committee met by teleconference on Thursday, November 7, 1996. The meeting was led by PT Committee Chair Ms. Andrea M. Jirka of the U.S. Environmental Protection Agency (USEPA) Region 7, Environmental Services Division. A list of action items is given in Attachment A. A list of participants is given in Attachment B. An agenda for the teleconference is given in Attachment C.

INTRODUCTION

The principle purposes of the meeting were to further discuss the matter of failed studies and to perform a detailed review of Chapter 2, "Proficiency Testing Program." Specific items of discussion are as follows:

- ! <u>Failed Studies</u> -- Will the PT Committee defer to the Accreditation Process Committee on the allowable number of failed studies?
- ! Shall the PT Committee deal with the requirements and/or procedures for "recovery" after a laboratory fails a performance testing study?
- ! Chapter 2 -- Are there additions or deletions to the chapter? Are there items that were eliminated previously that should be restored to the chapter?

ADMINISTRATIVE

The minutes of the teleconferences of October 10 and 24, 1996, were reviewed and discussed. The minutes of both meetings were approved as written.

The meeting to be held in Phoenix, AZ was discussed briefly. It was noted that the reservation at the Lexington Hotel is in the name of the Arizona Department of Health.

NEW INFORMATION

Ms. Jirka noted that computer disks loaded with the revised standards have been sent to all members of the committee. Comments on the standards are to be sent to Mr. Matthew Caruso by December 1, 1996. These will be reviewed at the meeting of December 11, 1996 if time allows.

FOLLOW UP FROM LAST CALL

Failed Studies

Ms. Jirka raised the issue of failed studies. She asked if the PT Committee wants to defer to the Accreditation Process Committee on determining the number of failed studies that will result in loss of accreditation. Mr. Ted Coopwood responded that the number of failures that results in loss of accreditation should not be decided by the PT Committee, but that the PT Committee should feel free to made recommendations to the Accreditation Process Committee as to this number. It was noted that States will want to maintain some measure of control over the process, for example, by maintaining some involvement in the administration of the process. Mr. Coopwood added that the matter of enforcement will be left to the States, and ultimately they will determine what constitutes failure. Ms. Ann Rhyne added that it would be reasonable for the National Environmental Laboratory Accreditation Conference (NELAC) to make a recommendation to the States as to the ultimate limit on the number of acceptable or unacceptable failures, but that the States should have some flexibility about this number. Mr. Tom Coyner asked if a minimum performance guideline would be reasonable, and Mr. Coopwood answered in the affirmative. Ms. Jirka proposed wording for a recommendation: "For example, if a laboratory fails two consecutive studies, it is subject to revocation of its accreditation." Ms. Rhyne added that variance in USEPA regulations is normal.

Recovery from Failure

Next to be discussed was the matter of recovery from failure. Previously, it was agreed that two passing studies would result in recovery. Ms. Jirka and Ms. Rhyne will draft strawman guidelines regarding both failure and recovery from failure. These will include the following:

- ! Requirements for initial awarding of accreditation,
- ! Number of failures that will result in loss of accreditation, and
- ! Requirements for successful recovery from failure and reinstatement of accreditation.

Mr. Coopwood and Mr. Coyner will assist in preparing these guidelines, which are due to the PT Committee members for review by November 19, 1996.

Specification of Method

An additional issue raised was the matter of including "method" in the definition of the field of testing. The Accreditation Process Committee includes method in its definition of the field of testing while the PT Committee has agreed not to include method. Resolving this issue is further work for the harmonization team.

Availability of Performance Data

Another matter of concern is the degree of availability of a laboratory's analytical performance results. If the "raw" performance results were made available to the public, there is a good chance that these data could be used and/or interpreted improperly. Once such data were published, a laboratory would have great difficulty counteracting a misunderstanding or

presenting information that would qualify unusual or apparently erroneous results. Mr. Chuck Wibby indicated that there should be three levels of data:

- ! Pass/fail data that are available to the public through the National Data Base,
- ! "Massaged" data that are provided to the States, and
- ! "Raw" data that the provider maintains.

NEW DISCUSSION ITEMS

Review of Chapter 2

Ms. Jirka noted that the decisions from the last two calls had not yet been written into the chapter, but that the changes will be made.

<u>Section 2.0</u> -- There was general agreement that two or three sentences are needed in this introduction to set the goal for the chapter and to provide a mission statement. Committee members will think about this prior to a discussion at the Phoenix meeting.

Section 2.1, fourth paragraph, line 4 -- Mr. Caruso requested interpretation of the phrase "... each lot of samples may be used only once ..." It was noted that reuse of the same samples can reduce costs, but there is the possibility of laboratories recognizing patterns in multianalyte samples if they are used more than once. If the phrase is removed from the chapter, the provider could use the same sample repeatedly. Ms. Jirka suggested that wording be written to require that a sample not be used more than once in a given period of time and that the concentration(s) of the analyte(s) be verified before reuse. Other possible restrictions include spiking the sample before reuse to alter the concentration of one or more analytes or allowing the sample to be sent only to laboratories that have not received this same sample previously. Allowing such reuse would be especially desirable for samples that are difficult or costly to prepare such as dioxin samples. Ms. Rhyne will prepare wording dealing with these concerns for placement in Appendix B.

<u>Section 2.1, second-to-last paragraph</u> -- Mr. Caruso indicated that this paragraph belongs in the section on enrollment. Ms. Rhyne agreed.

<u>Section 2.2, first paragraph</u> -- This paragraph currently indicates four PT studies per year and needs to be changed to indicate two PT studies per year. (This will be changed throughout the document.)

<u>Section 2.2, second paragraph, line 4</u> -- Ms. Jirka proposed changing the word "program(s)" to fields of testing. There was general agreement to this change.

<u>Section 2.2, third paragraph, line 2</u> -- Mr. Coopwood suggested that "NELAC-approved" be changed to "NELAP-approved."

<u>Section 2.3, first paragraph, line 1</u> -- Ms. Rhyne noted that the word "four" should be changed to "two."

<u>Section 2.3, first paragraph, line 7</u> -- Ms. Jirka recommended that the words "must attest to the fact that" be changed to "should assure that."

<u>Section 2.3, last paragraph</u> -- Ms. Rhyne noted that a discussion of recordkeeping does not fit well in this part of the document and should be placed in Section 2.3, "Requirement for Testing PT Samples." It was further suggested that this topic be covered in a separate paragraph. It was noted that this topic was included here to be consistent with regulations on data preservation. Mr. Coyner indicated that it was acceptable to leave this discussion in its present location. Ms. Rhyne suggested that she leave this discussion in its present location, but that she shorten and generalize it. All were in agreement with this suggestion.

Section 2.4 -- Mr. Coyner and Mr. Wibby plan to prepare an appendix to cover the criteria for evaluating PT sample results. Ms. Jirka noted that it would be important and useful to get EPA input for this topic since, within EPA, there are a variety of PT programs and few of these are evaluated in the same way. It will be difficult to get quick agreement between programs, and it is likely that different programs may go in different directions for a period of time. The PT Committee should develop "default" criteria, which would apply in those cases where the EPA programs do not specify their own criteria. Mr. Coyner and Mr. Wibby volunteered to prepare a general discussion of this issue for the body of the chapter and a detailed discussion for a new appendix. The general discussion for the body of the chapter is to be completed by December 11, 1996. Mr. Caruso will provide verbiage from New York State documents, which may be helpful. Ms. Jirka suggested that someone from the USEPA National Exposure Research Laboratory (NERL) be asked to assist. Ms. Jirka will ask Mr. Bob Graves to suggest someone. She will also see whether Dr. Barbara Erickson wants to work on this. Mr. Coopwood added that the National Environmental Laboratory Accreditation Program (NELAP) is to cover all USEPA regulatory, environmental programs and that others, such as the Resource Conservation and Recovery Act (RCRA), wish to be included.

It was noted that references to other chapters should be included in this section.

<u>Section 2.4.2, first and second paragraphs</u> -- It was noted that both paragraphs need to be rewritten. Ms. Rhyne agreed to perform this task. Mr. Caruso suggested that the discussion of "remedial action" be expanded to present more detail on the result(s) of such action.

<u>Chapter 2, general observations</u> -- It was noted that the chapter needs to concentrate on general program concepts and that details should only appear in the appendices. Ms. Jirka indicated that it was important to include a "skeleton" description of the program operation in the base chapter. She added that the chapter should include a description of the relationship between NELAC, NELAC providers, the States, and the laboratories. All were in agreement with these thoughts.

NEXT MEETING

The next meeting is scheduled from 3 to 5 p.m. Eastern Standard Time (EST) on Thursday, November 21, 1996. The PT Committee membership is to discuss the draft revision of Section 2.4.2 as well as the materials to be placed in Appendices A and B, which are to be provided by the respective subcommittees.

ACTION ITEMS Proficiency Testing Committee November 21, 1996

ACTION	Date Completed
PT committee members will review materials prepared and provided by subcommittees for inclusion in Appendices A and B for discussion on 11/21/96.	
Individuals and groups will write or rewrite sections of the base chapter and/or appendices as assigned for discussion on 11/21/96 or 12/11/96.	

List of Participants Proficiency Testing Committee Teleconference November 7, 1996

Name	Affiliation	Communication Numbers
Andrea M. Jirka, Chair	USEPA Region 7, Environmental Services Division	T: 913-551-5091 F: 913-551-5218 E: jirka.andrea@epamail.epa.gov
Wendy Blake-Coleman (invited)	U.S. EPA Office of Water	T: 202/260-5680 F: 202/260-7926 E: blake-coleman.wendy@epamail.epa.gov
George Breuer	University of Iowa Hygienic Laboratory	T: 319-335-4500 F: 319-335-4600 E: gbreuer@uhl.uiowa.edu
Matthew Caruso	NYS Dept. of Health Env. Lab. Approval Program	T: 518-485-5570 F: 518-485-5568 E: mnc01@health.state.ny.us
Ted Coopwood, NELAC Executive Sec'y	EPA, Office of Radiation and Indoor Air	T: 202-233-9358 F: 202-233-9651 E: coopwood.theordore@epamail.epa.gov
Tom V. Coyner	Analytical Products Group, Inc.	T: 614-423-4200 F: 614-423-5588 E: apg@citynet.net
Barbara J. Erickson (absent)	AZ Dept. Health Svcs./State Lab Svcs./Lab Licensure & Certification	T: 602-542-1194 F: 602-542-1169 E: bericks@hs.state.az.us
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PT Conference Call Thursday, Nov. 7, 1996; 3:00-5:00 EST (2:00 CST, 1:00 MST, 12:00 PST)

ADMINISTRATIVE

- Review minutes from Oct. 10 and Oct. 24 (Contact Bill Gutknecht if you don't receive them by Wednesday morning.)
- Any questions re: Phoenix meeting?

NEW INFORMATION

- Revised standards disks distributed
- Comments to me per request
- Do we want to review them as a group?

FOLLOWUP FROM LAST CALL

- Will we defer to the Accreditation Process Committee on the allowable number of failed studies?
- Do we want to cover "recovery" after a lab fails a PT study?

NEW ITEMS

- Detailed review of Chapter 2
- Additions or deletions? (It is understood that the chapter will be revised to reflect decisions from our last call.)
- Previous version: Did we eliminate anything that should be included?
- Subcommittee draft of Appendix A discussion
- Subcommittee draft of Appendix B discussion

SUMMARY AND REVIEW OF ACTION ITEMS

FOR NEXT TIME

- Think about agenda items for the Phoenix meeting.